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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 863,804	05 24 2001	Malcolm Wilson Moon	038602-1153	8901

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EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/863,804

Applicant(s)

MOON ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 4-5, 9, 14, 16-19, and 24-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, 10-13, 15 and 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-36 are pending in the current application. Claims 4-5, 9, 14, 16-19, and 24-36 drawn to a nonelected invention are withdrawn from further consideration.

Claims 1-4, 6-8, 10-13, 15, and 20-23 are rejected.

***Election/Restrictions***

Applicant's election with traverse of Invention I, claims 1-23, and the elected species of example 2 (page 46) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the examiner. This is not found persuasive because the independent and distinct inventions would require different searching strategies for each group. Searching all inventions would require separate searches in the classification system (the compounds and processes of making the compounds are searched in multiple subclasses in classes 544 and 548, while the methods of use are searched in multiple subclasses of class 514). Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

***Generic Concept***

The election of example 2, page 46, namely (3Z)-3-[(3,5-dimethyl-1H-pyrrol-2-yl)-methylidene]-1-(1-pyrrolidinylmethyl)-1,3-dihydro-2H-indol-2-one, has resulted in the following generic concept:

The compound of formula (I) as found in claim 1 wherein:

$R^3, R^4, R^5, R^6, R^7, R^8, R^9, R^{10}$ , and  $R^{1'}$  are as found in claim 1.

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**R<sup>3</sup>** and **R<sup>4</sup>** form un-substituted pyrrolidin-1-yl.

The remaining subject matter of claims 1-3, 6-8, 10-13, 15, and 20-23 that is not drawn to the elected invention identified supra and the subject matter of claims 4-5, 9, 14, 16-19, and 24-36 stand withdrawn from consideration as being drawn to a non-elected invention, 37 CFR 1.142(b). The withdrawn subject matter of claims 1-23 is properly restricted as it differs materially in structure and element from the elected subject matter identified supra so as to be patentably distinct there from. A reference, which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. Accordingly, restriction, as has been required, is proper.

### ***Objections***

Claims 1-3, 6-8, 10-13, 15, and 20-23 are objected to as containing non-elected subject matter.

### ***Specification***

The table on page 88 is not numbered. If this table is a continuation of Table 1 on page 87, the page should be amended to state this. If this is a separate table, the page should be amended to state "Table II," and the table on page 89 should be amended to state "Table III." Appropriate correction is required.

The paragraph starting on line 7 of page 89 is objected to because of the statement, "any clones, DNA or amino acid sequences which are functionally equivalent are within the scope of the invention." Since the specification does not discuss any clones, DNA or amino acid sequences, it is impossible to have any functional equivalents. This statement should be omitted. This paragraph is also objected to

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because of the reference to accompanying drawings. There were no drawings received with this application, therefore, this reference should be omitted.

### ***Double Patenting***

Claim 1-3, 6-8, 10-13, 15, and 20-23 of this application conflict with claims 1-9 of Application No. 09/863905. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

### **Statutory type (35 U.S.C. 101) double patenting**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 6, 8, 15, 21, and 23 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2, 4, 5, 7, and 9, respectively, of co-pending Application No. 09/863905. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

#### **Non-statutory double patenting**

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7, 10-13, 20, and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 1, 3, 6, and 8 of co-pending Application No. 09/863905. Specifically, claims 1-3 and 10-13 are rejected over claim 1 of co-pending Application No. 09/863905, claim 7 is rejected over the co-pending application's claim 3, claim 20 is rejected over the co-pending application's claim 6, and claim 22 is rejected over co-pending application's claim 8. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants claims 1-3, 7, 10-13, 20 and 22 teach the compound of formula (I) wherein  $R^{1'}$  can be hydrogen or alkyl (claims 1-3) and pharmaceutical compositions of the compound of formula (I) (claim 20) which can be administered parentally (claim 22). Applicant further limits the compound of formula (I) to compounds where  $R^3$ ,  $R^4$ ,  $R^5$ ,  $R^6$ ,  $R^7$ , and  $R^9$  are hydrogen and  $R^8$  and  $R^{10}$  are unsubstituted lower alkyl (claims 7 and 10) and where  $R^9$  is C-amido or lower alkyl substituted with carboxy (claims 11-13).

Claims 1, 3, 6 and 8 in co-pending Application No. 09/863905 disclose the compound of (I) which has hydrogen in the same position as that of  $R^{1'}$  in the instantly claimed compound of formula (I) (claim 1) and pharmaceutical compositions of the compound of formula (I) (claim 6) which can be administered parentally (claim 8). Co-pending Application No. 09/863905 further limits the compound of formula (I) to compounds where  $R^3$ ,  $R^4$ ,  $R^5$ ,  $R^6$ ,  $R^7$ , and  $R^9$  are hydrogen and  $R^8$  and  $R^{10}$  are unsubstituted lower alkyl (claim 3).

The difference between the claims at issue and the co-pending Application No. 09/863905 is that hydrogen must be in the position where  $R^{1'}$  is in the instant claims, and  $R^{1'}$  in the instant claims may be hydrogen or alkyl. In regards to instant claims 11-

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13, claim 1 of the co-pending application encompasses this embodiment, but there is no further limiting claim in co-pending Application No. 09/863905 for R<sup>9</sup> to be C-amido or lower alkyl substituted with carboxy.

However, it would have been obvious to someone of ordinary skill in the art, when faced with co-pending Application No. 09/863905 to prepare compounds where one of the hydrogens on the methyl of the 1-pyrrolidinylmethyl of the compound of formula (I) would be replaced with methyl (applicant is currently claiming alkyl which encompasses methyl) since it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). In regards to R<sup>9</sup>, it would have been obvious to prepare compounds where R<sup>9</sup> is C-amido or lower alkyl substituted with carboxy since this is encompassed by claim 1 of the co-pending application and is a preferred substituent as is seen on page 2 and 3 [0028] of the co-pending application. The motivation to make the instantly claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., inhibition of protein kinase).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703)


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605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.

  
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